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The Creation of Linear Contiguous Lesions in the Atria With an Expandable Loop Catheter

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OBJECTIVES This article describes a catheter system designed to create linear atrial lesions and identifies electrophysiologic markers that are associated with the creation of linear lesions.

BACKGROUND Atrial fibrillation (Afib) is the most common arrhythmia in humans and causes a significant morbidity. The success of surgical interventions has provided the impetus for the development of a catheter-based approach for the ablation of Afib.

METHODS We tested a catheter system with 24 4-mm ring electrodes that can create loops in the atria. The electrodes can be used to record electrical activity and deliver radiofrequency power for ablation. In 33 dogs, 82 linear lesions were generated using three power titration protocols: fixed levels, manual titration guided by local electrogram activity and temperature control. Bipolar activity was recorded from the 24 electrodes before, during and after lesion generation. Data were gathered regarding lesion contiguity, transmurality and dimensions; the changes in local electrical activity amplitude; the incidence rate of rapid impedance rises and desiccation or char formation; and rhythm outcomes.

RESULTS Catheter deployment usually requires <60 s. Linear lesions (12 to 16 cm in length and 6 ± 2 mm wide) can be generated in 24 to 48 min without moving the catheter. Effective lesion formation can be predicted by a decrease of greater than 50% in the amplitude of bipolar recordings. Splitting or fragmentation of the electrogram and increasing pacing threshold (3.1 ± 3.3 mV to 7.1 ± 3.8 mV, $p < 0.01$) are indicative of effective lesion formation. Impedance rises and char formation occurred at 91 ± 12°C. Linear lesion creation does not result in the initiation of Afib. However, atrial flutter was recorded after the completion of the final lesion in 3/12 hearts. When using temperature control, no char was noted in the left atrium, whereas 8% of the right atrium burns had char.

CONCLUSIONS This adjustable loop catheter forces the atrial tissue to conform around the catheter and is capable of producing linear, contiguous lesions up to 16 cm long with minimal effort and radiation exposure. Pacing thresholds and electrogram amplitude and character are markers of effective lesion formation. Although Afib could not be induced after lesion set completion, sustained atrial flutter could be induced in 25% of the hearts. (J Am Coll Cardiol 1999;33: 972–84) © 1999 by the American College of Cardiology

Currently, the Maze operation is considered to be the most effective treatment of chronic atrial fibrillation (Afib) with the highest long-term success rate, over 90% in selected series (1,2). In recent years we have witnessed the expanding use of transcatheter ablation to replace surgical therapy for arrhythmias. A percutaneous transvascular catheter approach to ablate Afib by separating atrial tissue with linear RF lesions, if effective even in a select patient population, would be a significant achievement in the treatment of this highly prevalent disorder.

The goal of catheter-based ablation of Afib should be safe minimal tissue destruction allowing for the restoration of sinus rhythm under autonomic nervous system control combined with recovery of atrial mechanical transport to prevent the development of a thromboembolic event and provide hemodynamic benefits for the patient. The atrial chambers are globular, elastic and only a few millimeters thick. Therefore, we hypothesized that a catheter system that creates adjustable loops in dynamic contact with the atrial walls is most likely to be able to adapt to the atrial structure and create good contact for ablating and recording. This article summarizes our experience using a catheter technology that was designed to create linear contiguous lesions in both atria.

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Abbreviations and Acronyms

Afib	= atrial fibrillation
ANOVA	= analysis of variance
IVC	= inferior vena cava
LA	= left atrium/atrial
LAH	= left atrial horizontal lesion
LAV	= left atrial vertical lesion
LEA	= local electrical activity
MV	= mitral valve
PV	= pulmonary vein
RA	= right atrium/atrial
RAA	= right atrial appendage
RAI	= right atrial isthmus lesion
RF	= radiofrequency
TEE	= transesophageal echocardiography
TV	= tricuspid valve

METHODS

The Afib ablation system. The catheters were constructed by EPT/Boston Scientific Corporation and consist of three parts:

1. *Catheter*: Two versions of a catheter with 24 ablating/recording ring electrodes were used (Fig. 1). One version has a monorail ring at its distal tip through which a guidewire is threaded (11 procedures) (3). A second generation has a guidewire permanently attached to its distal tip (22 procedures). We have tested the system with and without 24 thermocouple temperature sensors placed under the center of each of the ring electrodes along the outer surface of deflection.
2. *Guidewire*: A long, soft guidewire enables deflection of the distal tip of the catheter. The first version threads through the monorail and has a ball and a soft floppy pigtail on its end; the second catheter's guidewire is permanently attached to the distal tip.
3. *Sheaths*: The system uses a variety of 70-cm 11-F guiding sheaths with various angular bends at the distal end. Each sheath is equipped with a central port, a locking hemostatic seal mechanism and a side-arm infusion port.

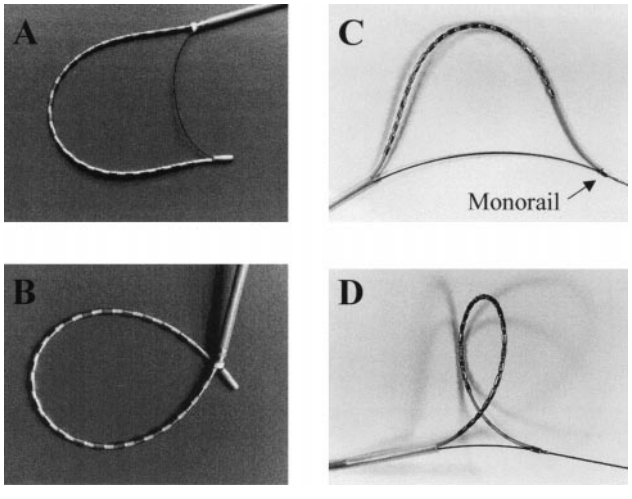

Figure 1. The two versions of the adjustable loop catheter. The fixed-tip **(A, B)** and monorail **(C, D)** systems are shown. The size of the loop can be adjusted by retracting the catheter into or pushing it further out of the guiding sheath.

Depending on the magnitude of the guidewire retraction and the size of the catheter portion extending from the sheath, the electrode portion of the catheter can form loops of various sizes. The body of the catheter applies pressure on the thin atrial walls and forces them to stretch around the catheter, maintaining consistent electrode–tissue contact along the entire length of the ablation portion of the catheter. Because the forces that are applied to the atrial walls are distributed along the catheter shaft around the loop, it is presumed that no single point is exposed to excessive forces. The locking mechanism holds the catheter and guidewire firmly in position.

Experimental testing of the Afib ablation catheter. All procedures were performed in compliance with the American Heart Association's guidelines for animal research and were approved by the University of Illinois at Chicago's Animal Care Committee. Dogs (25 to 35 kg) were premedicated with Nembutal (0.5 cc/kg) and transported to the laboratory, where anesthesia was maintained with halothane (1 to 1.5%) and O_2 (2 liter/min). The femoral vein was cannulated with a self-sealed 14-F short access sheath. A precurved 70-cm 11-F guiding sheath was inserted via the access sheath into the right atrium (RA) or the left atrium (LA). For LA placement, transseptal cannulation was achieved via the Brockenbrough technique using a specially designed dilator and a long transseptal needle under transesophageal echocardiographic (TEE) guidance. In addition, the jugular and femoral veins were cannulated and 6-F quadripolar catheters were placed in the coronary sinus and the high RA. After the procedures, the hearts were excised and examined for evidence of perforation of or damage to the valves, main vessels, nerve trunks around the heart and chamber walls.

Catheter positioning. Predetermined anatomical targets were chosen on the basis of the surgical Maze lesion locations, the mobility of the catheter and the ability of the catheter to adapt to the right and left atria. Various combinations of the following linear lesions were generated:

- *RA Loop*: A circular lesion from the anterior septal tricuspid valve (TV) to the right atrial appendage (RAA) to the superior vena cava and back to the inferior vena cava (IVC).
- *RAI*: A RA isthmus lesion where the catheter is looped into the right ventricle with the ablation electrodes across the TV ring extending into the IVC.
- *LAH*: A circular horizontal lesion placed under the pulmonary veins (PVs) in the mid-LA, above the mitral valve (MV), as indicated by a coronary sinus catheter and

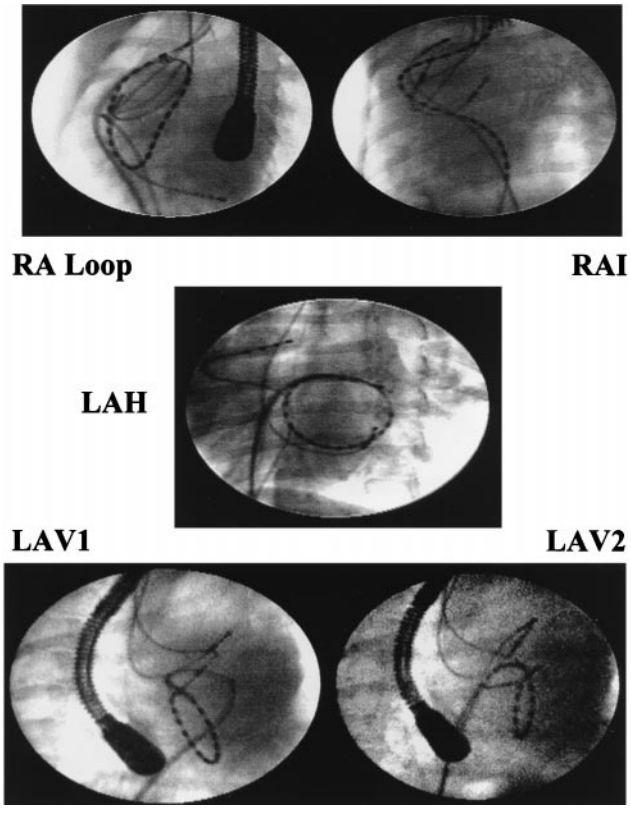

Figure 2. Fluoroscopic views of the catheter within the atria. The five locations where linear lesions were created are shown. Each lesion's relationship to cardiac anatomic landmarks is described in the text. LAH = left atrial horizontal lesion; LAV = left atrial vertical lesion; RA = right atrial; RAI = RA isthmus lesion.

the atrial and ventricular electrograms recorded from each of the 24 electrodes on the catheter.

- *LAV1*: A vertical lesion extending from the MV annulus medial of the PVs.
- *LAV2*: A vertical lesion extending from the MV to the LA appendage, lateral of the PVs.

Figure 2 depicts representative fluoroscopic images of the catheter positions for each lesion. An important factor in catheter positioning is the ability to reproduce placement in specific anatomic locations in different hearts. When deflected, the catheter tends to settle in the position with the largest circumference. However, by positioning the sheath at different levels, a variety of positions can be achieved in both the right and left atria.

In five dogs, the time required to place the catheter (with the guidewire fixed to the tip) in the RA Loop and the LAH position was documented. The time was measured from insertion of the catheter into the sheath until the catheter was firmly placed in the predefined location. In addition, the time needed to retract the catheter back into the sheath was recorded, and the total duration of fluoroscopic exposure was measured. A total of 34 catheter placements were timed. Continuous fluoroscopic images were recorded for each positioning effort, and successive attempts at positioning were compared to verify proper positioning. Electrical activity was recorded and was used to verify correct anatomical placement with respect to the atrioventricular ring. After the final placement, lesions were generated in each of the hearts. The hearts were excised, and the lesions were used to verify the anatomic positioning.

Lesion formation. In the 33 dogs, a total of 82 linear lesions were generated in the RA (44 lesions) and LA (38 lesions). Radiofrequency (RF) power was delivered sequentially via each electrode using three protocols including:

- *Power (21 dogs, 61 linear lesions, Radionics generator)*: Delivering power for 40 s at each of two power levels (5 then 10 W or 10 then 20 W) for a total of 80 s.
- *Amplitude (eight dogs, 13 linear lesions, Radionics or EPT generator)*: Titrating power from 0 to 50 W for 120 s based on online changes in local electrical activity recordings.
- *Temperature (five dogs, eight linear lesions, EPT generator)*: Titrating power from 0 to 50 W for 60 s to maintain a measurement of 70°C from the thermocouple on the ablating electrode.

Therefore, the maximum overall dwell times for ablating via all 24 electrodes were 24, 32 and 48 min for the temperature, power and amplitude protocols, respectively. In some cases the dwell times during ablation were less, if the atrium was small and required ablation with less than 24 electrodes to complete a linear lesion. One dog received lesions using two different power protocols (amplitude and temperature). Bipolar recordings from the 24 electrodes were obtained from overlapping electrode pairs (1–2, 2–3 . . . 22–23, 23–24) before, during and after lesion generation. In 31 ablation procedures (80 lesions), the incidence of rapid impedance rises to $>200\ \Omega$ was documented.

In six dogs, nine linear lesions were created, and the maximum power and maximum temperature were recorded. The amplitude of the atrial electrical activity was measured before and after lesion generation at each of the bipolar electrodes at fixed amplification and filtering (30 to 500 Hz), and the percent decrease was calculated. After excision, the hearts were soaked in tetrazolium blue stain for 8 h. The width and length of each individual lesion and the total linear lesion length were measured. The quality of each of the individual lesions with respect to contiguity, transmurality and desiccation or char formation was assessed. The lesions were defined as transmural and contiguous if no surviving muscle could be seen between the lesions and clear contiguous lesions could be seen on the epicardial surface. Char was defined as loosely adherent material that can be easily dislodged from its underlying tissue; desiccation was defined as tightly adherent, shallow, discolored material that is firmly attached to the underlying tissue. For 11 lesions created in eight dogs with amplitude or temperature power delivery protocols, each individual lesion was categorized as

follows: type 0—no identifiable lesion despite power application; type 1—minor superficial lesion formation that is neither contiguous nor transmural; type 2—lesion that is either contiguous or transmural; type 3—lesion that is both contiguous and transmural (the ideal lesion type); type 4—lesion that is contiguous and transmural but has adherent desiccation, and type 5—lesion that is contiguous, transmural and covered with loosely attached char.

In seven dogs, the average heart rate and P-R interval was calculated before and after generating a set of linear lesions.

In three dogs (152 individual burns), bipolar pacing threshold values were obtained by pacing (pulse width = 2 ms, cycle length = 300 ms) between two adjacent electrodes before and after applying RF power to the cathodal electrode, without moving the catheter.

Rhythm outcomes. In 12 dogs, 50-ms cycle length burst pacing was applied for 5 s to the RAA before and after the completion of 31 linear lesions, and the resulting rhythm was recorded. The rhythm was categorized as sinus, Afib or atrial flutter. Its duration was defined as sustained (lasting >180 s) or nonsustained (lasting 30 to 180 s).

Epicardial mapping. To examine the effects of lesions on local electrical activity, the RA and LA were mapped before and after the creation of RA and LA lesions. The chest and pericardium were opened via a median sternotomy, and a handheld high density mapping plaque (112 bipolar electrodes) was placed on the LA and RA surfaces. Activation of the RA and LA was recorded during 400-ms pacing from the RA and LA appendages. The plaque was removed, and the chest was clamped closed. Lesions were created with the catheter from the endocardial surface across the areas where the plaque had been placed on the RA and LA. The chest was reopened, the plaques were repositioned in the same areas as before ablation and electrical activity was recorded during 400-ms pacing from the RA and LA appendages.

Statistical analysis. Summary data are expressed as raw mean value ± SD. Since the focus of this report is on the methodology for the creation of contiguous transmural linear lesions, we analyzed the effects of different power titration techniques by assessing the local electrical activity pre and post individual lesion creation and by defining the temperature needed to create the desired lesions. The continuous data were analyzed using a nested random effects analysis of variance (ANOVA) model that treats the dogs as blocks (random) and the observations from each dog as a nested subsample. The local electrical activity (LEA) group and atrium were also included as factors in the ANOVA. The p values were considered significant if they met the level of 0.025 since two variables, namely power and temperature, were simultaneously studied. This adjusted level ensures, by Bonferroni method, an overall significance of 0.05. A McNemar's chi-square test was used to compare arrhythmia inducibility before and after lesion generation.

RESULTS

Safety. In the 33 dogs, no atrial wall tears occurred due to the formation of a loop. There were no instances of perforation of or acute damage to the valves, main vessels or chamber walls. Transesophageal echocardiography and fluoroscopic visualization did not show evidence of pericardial effusion or tamponade after lesion generation. No acute mitral or tricuspid regurgitation was recorded using TEE Doppler evaluation of valvular function. The catheter system did not become entrapped in the tricuspid or mitral valve apparatus. However, if a standard electrophysiologic catheter was inserted after the deployment of the ablation catheter, attempts to withdraw the Afib ablation catheter before the removal of the recording catheter could result in entrapment of the recording catheter within the loop of the Afib ablation catheter. To avoid such an event, catheters inserted into the chamber after deployment of the ablation catheter should be removed prior to the removal of the ablation catheter. If entrapment occurs, the ablation catheter can be pushed back into the chamber, and the other catheter can be removed. If the Afib ablation catheter is inserted into the LV across the mitral valve, it can interfere with proper mitral valve closure and cause mitral regurgitation. We have avoided this interference by using TEE monitoring of mitral function during the placement of the catheter in the LA. In seven dogs, the heart rate was 126 ± 19 beats per minute before ablation and 118 ± 36 afterwards (p = NS), and the P-R interval was 105 ± 19 ms before ablation and 109 ± 28 afterwards (p = NS). There was no evidence of third-degree atrioventricular block in any dogs.

Lesion formation: temperature, local electrogram reduction. Three protocols were used to manually titrate RF power. As shown in Table 1, power titration of 5 and 10 W resulted in 7% impedance rises. Power titration of 10 and 20 W resulted in a 14% incidence of impedance rise. Both temperature and local electrogram amplitude monitoring yielded low levels of impedance rises, 5% and 2%, respectively. Lesion character was divided into six categories. The ideal lesion (type 3) is contiguous and transmural, without any evidence of desiccation or char on either the tissue or the catheter. As shown in Figure 3, type 3 lesions were 44% of the total lesions generated with temperature-based titration and 46% of the lesions generated with 70% reduction of local electrogram amplitude. The average recorded temperature for these two protocols was 71 ± 7°C for type 3 lesions. If one combines type 3 and 4 lesions, the percent acceptable lesions increases to 70% and 57% for the temperature and the amplitude protocols, respectively. With temperature-guided power titration, in multiple cases the peak temperature exceeded the target temperature leading to overheating and impedance rises. Impedance rises and char formation (lesion type 5) were associated with temperatures of greater than 91 ± 12°C. As shown in Figure 4,

Table 1. Impedance Rises During Ablation

		Total: RA+LA				RA				LA			
Protocol	Hearts	Linear Lesions	Burns	Z Inc.	%	Linear Lesions	Burns	Z Inc.	%	Linear Lesions	Burns	Z Inc.	%
5 & 10 W	6	21	409	27	7	7	148	13	9	14	261	14	5
10 & 20 W	13	38	768	104	14	23	473	66	14	15	295	38	13
Amplitude	8	13	248	5	2	7	130	1	1	6	118	4	3
Temperature	5	8	161	8	5	5	93	6	6	3	68	2	3

Impedance rises with various power titration methods (31 dogs, 80 linear lesions).
Amplitude = power titrated until the local electrical activity amplitude decreased by 70%; LA = left atrium; RA = right atrium; Temperature = power titrated to maintain 70°C for 60 s; Z Inc. = impedance increase; % = percent of individual burns with an impedance rise.

inadequate lesions (type 0, 1 and 2) were associated with lower temperatures of 42 ± 3°C ($p < 0.000$, type 0 vs. type 3), 61 ± 11°C ($p < 0.000$, type 1 vs. type 3) and 68 ± 4°C (p = NS, type 2 vs. type 3). Overall, the average temperature was 74 ± 13°C and the average local electrogram reduction was 67 ± 34% for the lesions created with temperature or amplitude guidance.

Table 2 summarizes the data obtained using temperature control to generate linear lesions in the RA Loop versus LAH position. The total linear lesion length was 12.4 ± 1.3 cm in the RA vs. 16 ± 1.1 cm in the LA due to differences in the circumferential atrial size. Because the atrial size varied between dogs, the size of the loop needed to create the encircling lesions did not always require the use of all of the 24 electrodes. The power requirements in the LA were significantly lower than in the RA. This is likely related to variations in the degree of the catheter embedding into the atrial tissues, especially in the lateral regions of the LA. In these regions the power levels were often less than 10 W. If an impedance rise occurred, it frequently resulted in char formation as shown in Figure 5. The high average initial electrode–tissue impedance provides further evidence of tissue contact.

Data regarding the decrease in LEA postablation is summarized in Table 3. When postablation LEA was minimally decreased, the target temperature often was not achieved. These data correspond to the lower percentage of lesions that were transmural and contiguous when LEA decreased <50%. This observation contrasts with the achieved target temperature and high percentage of trans-

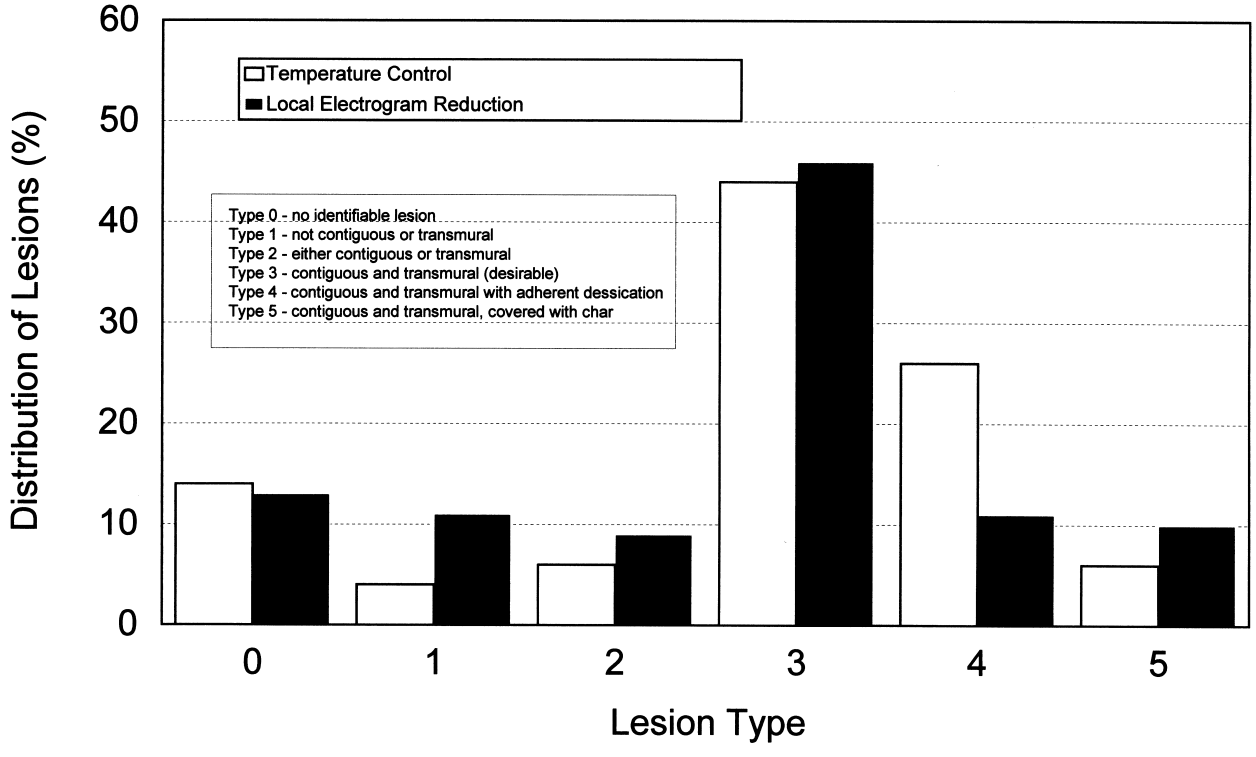

Figure 3. Distribution of individual (4-mm electrode) lesions. Seven linear lesions were created with the 70°C power protocol **(white bars),** and four linear lesions were generated with the 70% local electrogram recording reduction protocol **(black bars).** The majority of lesions were type 3, which are contiguous and transmural and exhibit no char.

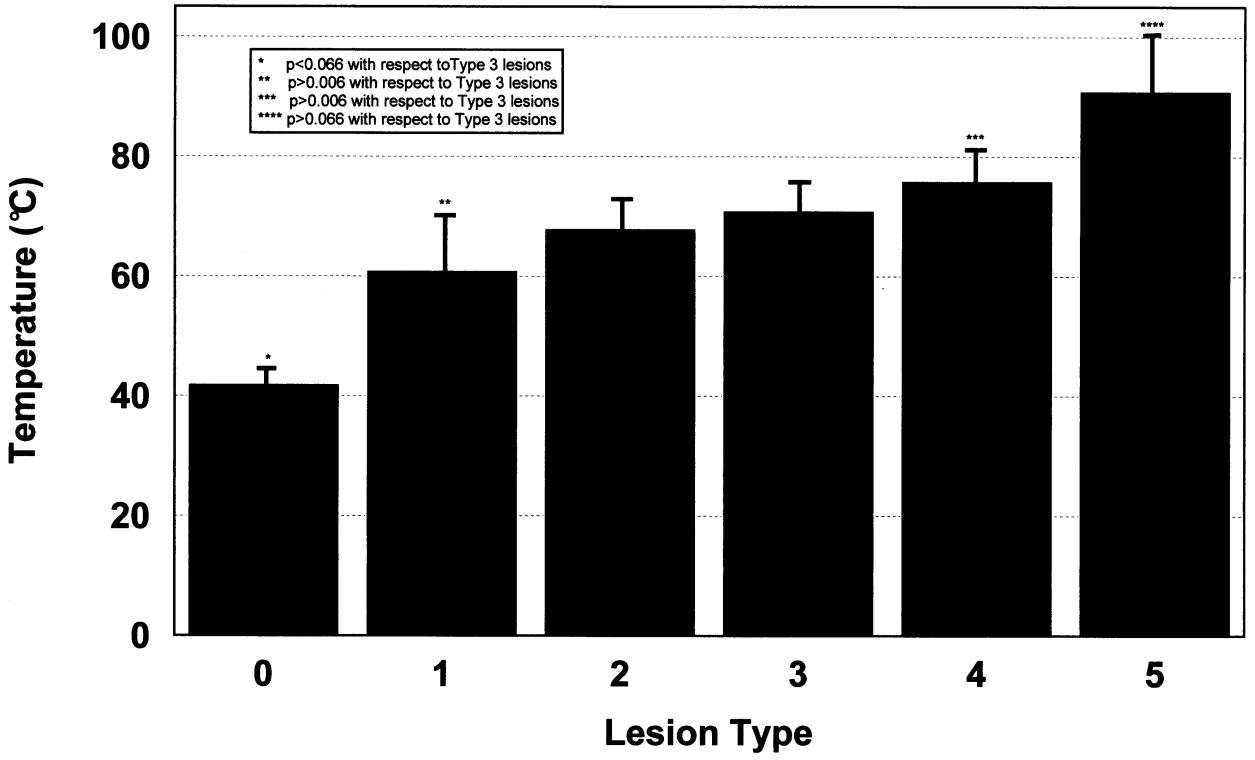

Figure 4. Temperature and individual (4-mm electrode) lesion types. The figure shows the distribution of the average maximum temperatures for type 0–5 individual lesions. Eleven linear lesions were created in eight dogs using a catheter with a thermistor on each individual electrode. Seven linear lesions were created with the 70°C power protocol, and four were generated with the 70% local electrogram recording reduction protocol. Type 3 lesions, which were created with an average temperature of 71 ± 7°C, exhibited no charring or impedance rises. Contiguous and transmural lesions were not formed at lower temperatures (types 0–2). Desiccation (type 4) and charring (type 5) occurred at higher temperatures.

mural and contiguous lesions associated with a LEA decrease between 50% and 100%. These data define the differences between poor and good tissue contact.

Pacing thresholds. In three dogs, cathodal pacing thresholds were obtained from each electrode (152 total). Average thresholds as baseline were 3.0 ± 3.2 mA and 3.2 ± 3.4 mA in the RA Loop and LAH positions, respectively. Thresholds increased to 6.2 ± 3.3 mA and 8.6 ± 4.2 mA postablation representing 205% and 272% increases, respectively, and corresponded to lesion types 3, 4, 5 and 6. The overall average thresholds before and after ablation for both atria combined were 3.1 ± 3.3 mA and 7.1 ± 3.8 mA ($p < 0.01$), which is a 388% increase.

Table 2. Lesion Generation With Temperature Control

	RA Loop (n = 4)	LAH (n = 2)
Total individual lesions	63	41
Maximum power (W)	21 ± 14	11 ± 6*
Maximum temperature (°C)	73 ± 8	70 ± 6
% decrease LEA	65 ± 42	66 ± 19
% contiguous	98	85
% transmural	97	90
% char	8	0
Width (mm)	6 ± 2	6 ± 2
Individual lesion length (mm)	6 ± 1	6 ± 1
Impedance (Ω)	131 ± 20	132 ± 12
Total linear lesion length (cm)	12.4 ± 1.3	16 ± 1.1*

* Designates $p \leq 0.05$ vs. circular lesion in the right atrium (RA Loop). Summary of parameters from six linear lesions generated in four dogs by titrating power from 0 to 50 W to maintain 70°C for 6 s. The statistics are listed as raw mean ± SD.

LAH = horizontal lesion in the left atrium; % decrease LEA = percent decrease in amplitude of local electrical activity after lesion creation.

Catheter positioning. Table 4 summarizes the time required to place and remove the catheter and the duration of radiation exposure in five dogs. Fluoroscopic video recordings and electrical recordings were used to verify that the placements were in the designated positions and were consistent. In addition, after removal of the hearts, the location of radiofrequency lesions confirmed the catheter positioning. Placement of this catheter technology in either the LAH or RA Loop positions averaged less than 1 min with minimal radiation exposure.

Recordings, pre-postablation changes and lesion characteristics. Figures 5 to 8 are examples of catheter positions, LEA recordings and pathological specimens from lesions created with the loop catheter design. In both the right and left atria, well defined local electrical recording is shown in

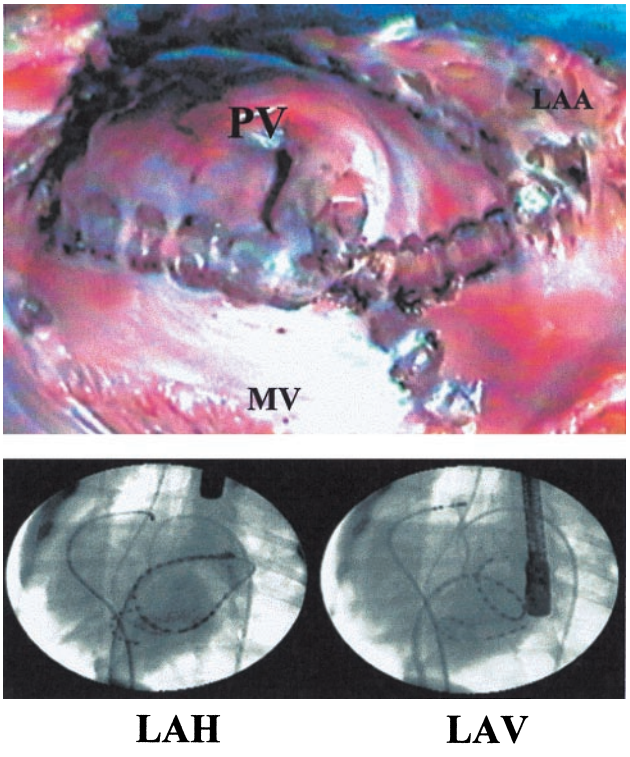

Figure 5. Left atrial horizontal (LAH) and vertical (LAV) positions: gross lesions with charring and corresponding fluoroscopic images. The tissue specimen illustrates an encircling lesion around the pulmonary veins (PV) and a vertical lateral lesion connecting the mitral ring to the encircling lesion. The lesions were generated with radiofrequency power titration without temperature control. The heavy char formation is a potential source for embolic stroke. LAA = left atrial appendage; MV = mitral valve.

Figures 6 and 7. Postablation, the local electrical recording was markedly decreased and became fractionated or split into two propagating wave fronts. Furthermore, as shown in Figure 7 the conduction time of the LA activation from the septum to the LA appendage was prolonged by 40 ms because of the encircling lesion above the mitral valve as shown in the pathological specimen. As shown in the examples provided in Figures 5, 7 and 8 using this catheter technology the pulmonary veins encircling lesion can be achieved with relative ease.

Epicardial maps. Figure 9 shows the distinct changes in local electrical activity recorded from the high density mapping plaque. After the creation of linear lesions, the conduction times across the lesions were markedly delayed, from 28 ms to 109 ms in the left atrium and from 40 ms to 158 ms in the right atrium, suggesting conduction block across the lesions.

Table 4. Catheter Placement

	Placement (s)	Removal (s)	Total Radiation (s)
RA (n = 23)	40 ± 33	8 ± 14	48 ± 36
LA (n = 11)	44 ± 18	9 ± 3	53 ± 17

Time in seconds required to place the catheter in a specific anatomic location, time needed to remove the catheter and total fluoroscopic imaging duration in five dogs. n = the number of placements.

Rhythm outcomes. Table 5 summarizes the rhythm post–burst pacing at baseline, after each individual linear lesion and at the end of the procedure for 12 dogs. In nine of the 12 dogs (75%), the rhythm was sinus with no other inducible rhythms at the end of the procedure. Sustained atrial flutter was recorded after 13/31 linear lesions (42%). After 4/7 (57%) LAH lesions and 4/5 (80%) first LAV lesions, sustained atrial flutter was inducible. After completion of all lesions, 3/12 dogs exhibited sustained atrial flutter. In these three dogs at baseline, one exhibited only sinus rhythm, one had sustained Afib and one had sustained atrial flutter. Atrial fibrillation was never a consequence of creating a linear lesion in any of the 12 dogs.

Atrial flutter. Atrial flutter circuits were both created and terminated by various linear lesions. In four dogs, the generation of a linear lesion in the LA resulted in the inducibility of sustained atrial flutter that was not inducible preablation. This was a LAH lesion in 2/4 cases and a LAV lesion in the remaining two dogs. In three of these four dogs, atrial flutter was noninducible after creating a single additional linear lesion (one RAI, two LAV), but no additional lesions were created in the fourth dog. In an additional dog, sustained atrial flutter was inducible at baseline, but only sinus rhythm was recorded after generating a LA linear lesion.

DISCUSSION

Following the work of Cox et al. (1,2), we have assumed that the ablation of Afib is likely to require lesions that are linear, contiguous and transmural, and terminate in a manner that prevents the formation of atrial flutter. How-

Table 3. Local Electrical Activity

Range of % ↓ in LEA	Average % ↓ LEA	Max Power (W)	Max Temperature (°C)	% With Char	% Cont	% Trans	% Cont & Trans
<50 (n = 40)	5 ± 49	17 ± 12	65 ± 16	3	65	63	60
50 to 100 (n = 135)	75 ± 15	15 ± 10	73 ± 11	4	90	88	87

The parameters are grouped according to the percentage decrease in the local electrical activity (LEA). These 175 individual lesions were created by using the temperature or amplitude power delivery protocols to create nine linear lesions in six hearts. The statistics are listed as raw mean ± SD.
Cont = contiguous; Trans = transmural.

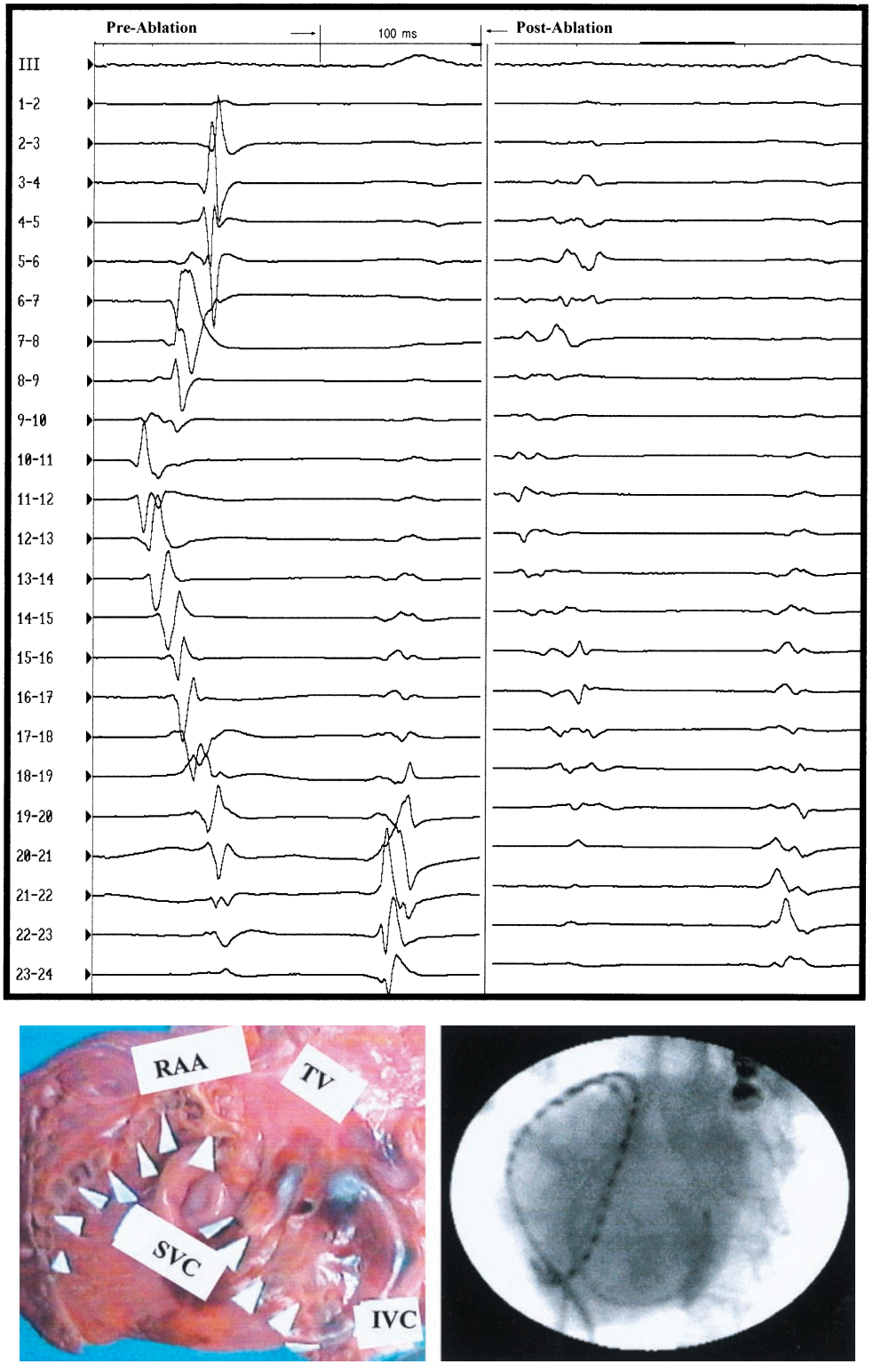

Figure 6. Right atrial (RA) loop position: preablation and postablation recordings, gross lesions and fluoroscopic image. Electrode 1 is located at the inferior vena cava (IVC) atrial junction (note the low amplitude recording at electrode pair 1–2). The recordings from electrodes 1 to 9 are from the IVC–superior vena cava (SVC) region of the atrium. Electrode pair 9–10 traverses the SVC as depicted by the low electrogram amplitude. Electrodes 10 to 12 display the earliest electrograms, from the sinus node region at the anterior junction of the SVC and right atrial appendage (RAA). The recordings 13 to 22 are from across the RAA, and the remaining recordings traverse the tricuspid ring into the right ventricle. In regions progressively closer to the atrioventricular junction, the amplitude of the ventricular wave increases. Postablation, the propagation of the right atrial depolarization sequence still initiates from the region recorded by electrodes 9 to 11. However, the creation of the lesion resulted in a marked decrease in the electrograms' amplitude and fragmentation of the local recordings. These double potentials coincide with the creation of contiguous linear lesions. TV = tricuspid valve.

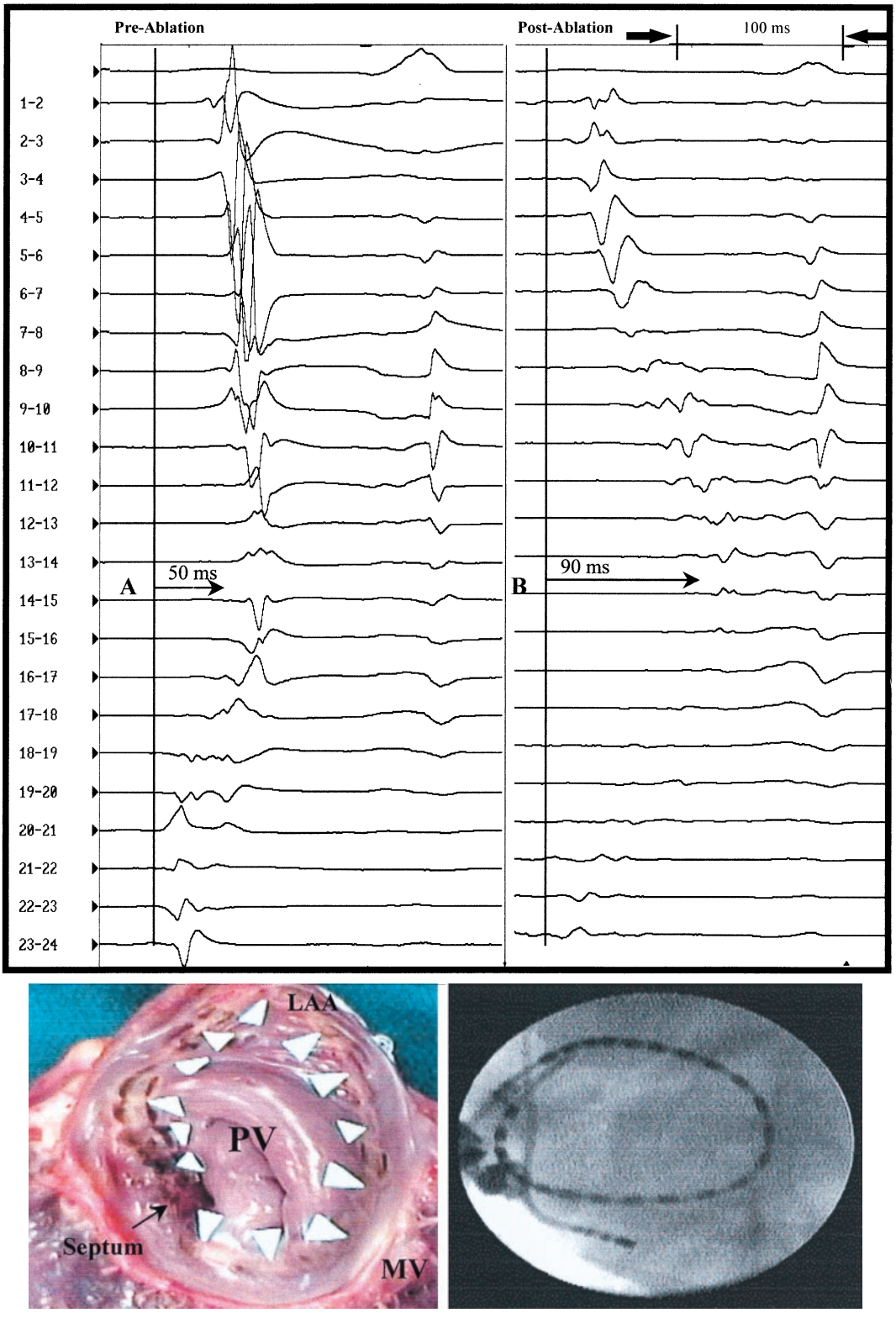

Figure 7. Left atrial horizontal position: pre-/postablation recordings, gross lesions and fluoroscopic image. The catheter was placed in a horizontal position superior to the mitral ring under the pulmonary veins (PV). Note the location of the coronary sinus catheter in relation to the ablation catheter. The distal and most proximal electrodes, 1 and 24, are both near the transeptal insertion site at the foramen ovale. The portion of the catheter positioned closer to the mitral ring (electrodes 7 to 13) recorded larger ventricular electrograms. The depolarization wavefront propagates from the septal region to the most distal recording within the left atrial appendage (LAA) in 50 ms. After radiofrequency ablation, the local electrogram amplitude decreased significantly. In addition, the recordings from electrodes 8 to 24 became fragmented, and the conduction time from the earliest to the latest electrode increased to 90 ms, 40 ms longer than preablation. These observations correspond to the linear contiguous lesions in the gross pathological photograph. MV = mitral valve.

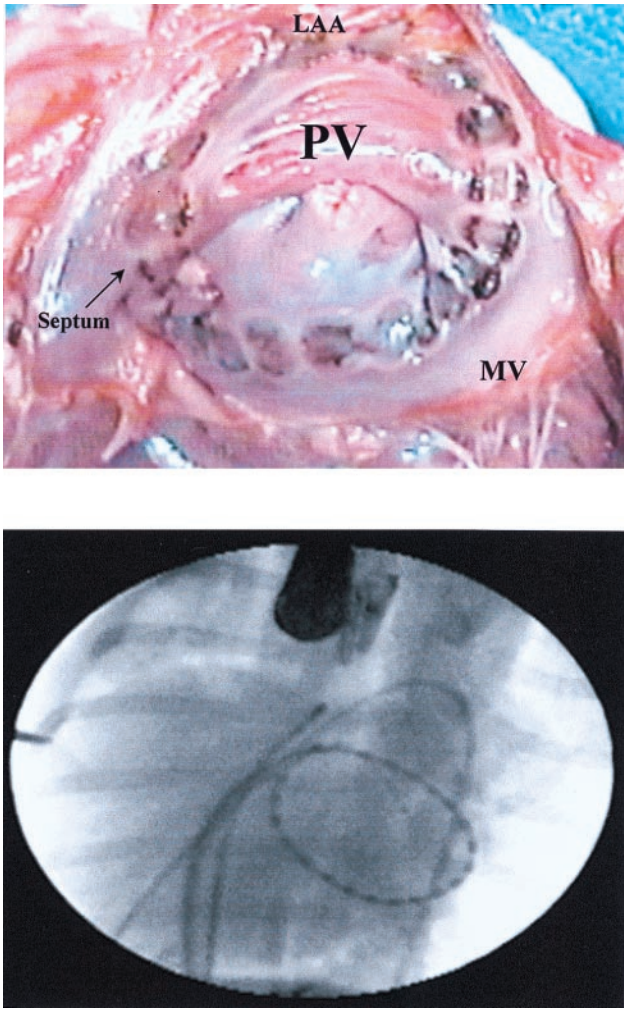

Figure 8. Left atrial horizontal position: gross lesions with charring and fluoroscopic image. This linear and contiguous encircling subpulmonary lesion was created with radiofrequency power titration of up to 20 W with no temperature control. Char was formed near the periphery of the electrode–tissue contact areas. The lesions are bridged with desiccated, blushed tissues between most of the individual burns. Abbreviations as in Figure 7.

ever, current catheter ablation technology is unlikely to allow the design flexibility capable of creating such lesions without inflating production costs, compounding complexity and compromising safety. A successful Afib ablation system might not totally eliminate the arrhythmia, but instead might increase drug efficacy, decrease the length of time and the incidence of paroxysmal Afib or convert sustained Afib to paroxysmal Afib. Since much is yet to be learned about the mechanism of Afib, a simple safe technology that provides both mapping and ablation capability should be used initially.

Safety. Having multiple ablation electrodes on a single shaft allows for minimal catheter manipulation in creating long linear lesions and, therefore, may reduce both thromboembolic risk and radiation exposure. Once the catheter is in place, it remains in position for the duration of the power application to all 24 electrodes. In this study using sequential power application to each electrode, the total dwell time during ablation varied between 24 and 48 min depending on the power protocol utilized.

This ablation system was placed in 33 dogs with no mechanical injuries to the atrial or ventricular tissues, no damage to the valvular structures and no entanglement of the catheter system with tissues. However, if an additional catheter is introduced into the cardiac chamber after the deployment of the Afib ablation catheter, this second catheter should be retracted before the removal of the Afib catheter. Though it did not occur in any of our procedures, with this system there is the potential for mechanical injury to occur across the intra-atrial septum. Once the guiding sheath is placed across the septum it must be maintained at this position, particularly during catheter manipulation. If the sheath is not kept across the atrial septum, expansion of the catheter loop could result in septal tearing. In addition, if the catheter is deployed across the mitral ring it may interfere with valvular closure.

Catheter positioning. Placement of this system in the atria usually required less than 1 min in this animal model. Although this system naturally creates loops at the points of maximal diameter, it can be positioned in various other anatomic locations by manipulating the guiding sheath. The catheter naturally adapts to the RA Loop and LAH positions, whereas the LA vertical positions usually require sheath manipulation. Poor contact can be improved without significantly changing the location of the lesion by simply expanding the size of the loop.

Lesion formation. The most important determinant in the effective creation of a RF lesion is the electrode–tissue contact. Using the variable loop concept, the globular-shaped atrial chambers will adapt around the catheter providing continuous contact. When using temperature control with this technology, over 90% of the lesions created in both atria were both contiguous and transmural; the incidence of impedance rises was minimized. The catheter can be used to create linear lesions 6 mm wide and up to 16 cm long with minimal manipulation. In this study, linear lesions were made by ablating individual electrodes. The time required to create an entire linear lesion could be greatly reduced by using a closed-loop system to simultaneously deliver RF power to multiple electrodes to maintain a set temperature.

Recordings. Using 4-mm ring electrodes separated at 4-mm intervals allows for discrete localized recording of electrical activity before, during and after ablation. Such recordings provide online monitoring of the lesion formation. A reduction of greater than 50% in the recorded electrogram is a good indication of effective lesion formation. When lesions are created during sinus rhythm or flutter, the formation of double potentials and fragmented electrical activity signifies transmural lesion creation. The

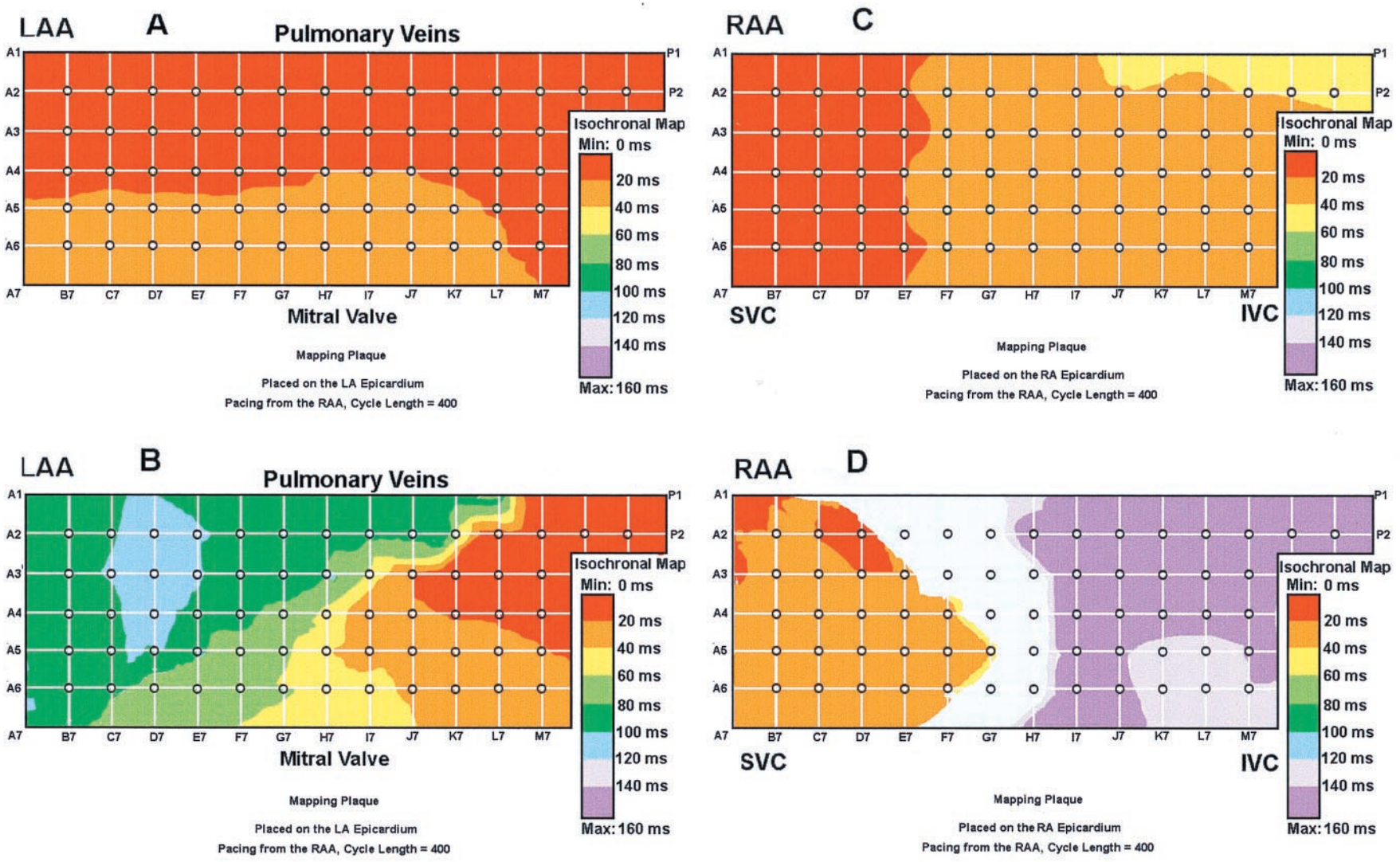

Figure 9. Epicardial electrical activity maps: before and after linear lesion creation. **(A)** An isochronal map of the left atrium (LA) during right atrial appendage (RAA) pacing at 400-ms cycle length. The mapping plaque was placed from the left atrial appendage (LAA) to the mitral valve ring around the atria with the pulmonary veins on the top of the plaque and mitral ring on the bottom extending to the atrial septum. The atrial activation progressed around the LA from two directions, anteriorly and posteriorly. The total LA activation lasted 28 ms. **(B)** A map obtained after creating a LA lesion bisecting the LAA circumferentially and vertically. The LA was activated from the atrial septum and reached the LAA in 109 ms. **(C)** An isochronal map of the right atrium (RA), paced from the RAA at 400-ms cycle length. The mapping plaque extended from the RAA **(top)** and superior vena cava (SVC) **(bottom)** to the tricuspid ring **(top right)** and inferior vena cava (IVC) **(right bottom)**. The atrium was progressively depolarized starting at the RAA and ending at the tricuspid ring with total activation time of 40 ms. **(D)** An isochronal map following the RA linear lesion, which bisects across the RAA. The atrial activation started at the RAA and progressed to the lateral wall. The white area represents the territory of recording electrodes on the plaque where no electrical activity could be detected. The lateral wall tissues closer to the tricuspid valve were activated after 158 ms.

Table 5. Rhythm Outcomes

	Baseline	RA Loop	RAI	LAH	1st LAV	2nd LAV	End
Sinus	5	10	3	3	1	—	9*
NS Fltr	3	—	—	—	—	1	—
S Fltr	2	2	1	4	4	2	3*
NS Afib	—	—	—	—	—	—	—
S Afib	2	—	—	—	—	—	—

*p is not significant comparing baseline versus after the completion of all the lesions. Five seconds of burst pacing was applied before creating any lesions and after each lesion. The table summarizes the rhythm status in 12 dogs at baseline before any lesions were created, after creating each individual linear lesion and at the end of all lesion generation.

Afib = atrial fibrillation; Baseline = before any lesions were made; End = after all lesions were created; Fltr = atrial flutter; LAH = circular horizontal left atrial lesion; LAV = one of two vertical left atrial lesions; NS = nonsustained (30 to 180 s); RAI = right atrial isthmus lesion; RA Loop = right atrial circular lesion; S = sustained (>180 s).

mechanism of this observation is likely related to the formation of a split atrial depolarization wavefront around the catheter as a result of the lesion. The recording of double potentials around an area of conduction block has been previously described by Feld and Shahandeh-Rad (4). Because these recordings are made from adjacent electrodes, the destruction of the tissue underneath and between these electrodes results in marked diminution of the recorded electrical activity. Further confirmation of tissue destruction is noted by the significant increase in the pacing threshold. The ability to retrieve discrete localized recordings from multiple electrodes provides atrial mapping capability and allows for safeguarding of the His bundle.

Rhythm outcome. After 75% of the ablation procedures, no arrhythmia was inducible. The most common arrhythmia induced during the ablation procedures was sustained atrial flutter, which was present after 42% of the individual linear lesions and at the conclusion of 3/12 ablation procedures. At baseline, these three hearts exhibited sinus rhythm, sustained Afib and sustained atrial flutter, respectively.

Atrial flutter circuits were created and terminated by linear lesion generation. In four dogs, the generation of a linear lesion in the LA resulted in the inducibility of sustained atrial flutter that was not inducible preablation. In three of these four dogs, atrial flutter was noninducible after creating a single additional linear lesion (1 RAI, 2 LAV). In an additional dog, sustained atrial flutter was inducible at baseline, but only sinus rhythm was recorded after creating a LAH lesion. In this study, Afib was never a consequence of creating a linear lesion. In fact, in one dog with inducible sustained Afib at baseline, the creation of linear lesions eliminated the Afib. Additional studies are needed to show that this technology and lesion set will be effective in ablating Afib in a chronic model before evaluating its efficacy in humans.

Atrial fibrillation ablation in humans. Recently several reports were presented supporting the notion that chronic Afib can be terminated in humans (5–7). Perhaps the most important conclusion to be drawn from these studies is that, despite the technological limitations and the uncertainty of the character of the lesions that were created, the investigators were still able to terminate Afib. Clearly, as we have learned from Cox et al., to achieve a high degree of success in most patients with chronic Afib, a careful Maze-type procedure may be necessary. A procedure that requires a thoracotomy may not allow for repeat surgery if the Afib recurs. Thus, an extensive and meticulous complete Maze procedure is required in every surgical patient to ensure the desired outcome. If catheter-based ablation can be safely developed, it would allow for extensive investigation into the mechanisms of Afib in humans.

Conclusions. In this study, we wished to define the feasibility of linear lesion generation in dogs and to describe the basic characteristics of a catheter system that will have the potential to ablate Afib by efficiently creating linear contiguous atrial lesions. Our present hypothesis is that successful ablation of Afib will require a system that is easy to manipulate, can conform to various atrial sizes and shapes and can create effective contact by maintaining firm and uniform catheter–tissue pressure. Firm contact with the atrial tissue during RF energy application increases the likelihood of transmural, contiguous lesion formation.

Although the results from animal studies may not be fully extrapolated to the human heart, this catheter technology shows great promise in creating the type of lesions that will likely be necessary to ablate Afib in humans. The data obtained with regard to linear lesion contiguity and transmurality, local electrogram changes and pacing thresholds reflect the results obtained from this specific catheter design and cannot be extrapolated to other designs.

The loop catheter system is capable of creating long linear lesions (12 to 16 cm) at predefined anatomic locations. The deployment of the catheter requires minimal radiation exposure. It caused no perforations or valvular injuries. However, the catheter could tear the septum if it is placed transseptally, the sheath is retracted into the RA and the catheter is deflected while still traversing the septal hole. In addition, if it is deployed across the mitral ring it may interfere with valvular closure. Once the catheter is positioned, no further movements are needed until the completion of the linear lesion. The methods described in this

report provide the operator with multiple means of assessing the quality of lesion formation. Ideal lesions are likely to result when thermistors are used to maintain the temperature at 70°C, the local electrical activity amplitude is reduced by 50% of its baseline value, splitting of the atrial depolarization is noted and the atrial pacing threshold increases. Atrial fibrillation was never a consequence of creating a linear lesion in any of the 12 dogs that were tested for inducible arrhythmia, but sustained atrial flutter was inducible after the completion of all the lesions in three dogs (25%).

Limitations. In these acute studies, the dogs were not anticoagulated. Long-term complications such as pericarditis or pericardial effusion could not be assessed, but there were no atrial perforations in any of the procedures. The potential correlation between the microscopic analysis of the tissues for lesion contiguity and transmurality and the inducibility of atrial flutter postablation was not assessed. However, the high density epicardial maps and the appearance of split potentials postablation both indicate the formation of conduction block across lesions. In those dogs with inducible atrial flutter, such flutter is likely a result of a reentry around an incomplete lesion. These ablation procedures were carried out in dogs with normal hearts. Further investigation of this technology and technique needs to be performed in a chronic model of Afib to assess its curative efficacy.

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